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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,297	12/19/2000	Genevieve Hansen	S-30025D	5673

22847 7590 12/19/2003

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EXAMINER

HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,297

Applicant(s)

HANSEN, GENEVIEVE

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

REQUEST FOR CONTINUED EXAMINATION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 September 2003 has been entered.

Status of the Claims

2. Applicant has canceled claims 20-41, and added new claims 42-55. Claims 42-55 are examined in the instant action. All rejections not addressed below have been withdrawn.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112-2

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1638

5. Claims 42, 43, 44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 42, and 51 (a) "a plant cell or tissue" should be "the plant cell or tissue", referring back to plant cell or tissue susceptible to AIN.

In claim 43, the term "mg/l" needs to be inserted after "0.1" and before "20", for clarification of the units.

In claim 44, the term "mg/l" needs to be inserted after "1" and before "10", for clarification of the units.

Claim 46, "said plant cell or tissue is cultivated on a medium which comprises silver nitrate" is unclear because the plant cell is already on medium contain silver nitrate. Does Applicant mean with without Agrobacterium?

Clarification and/or correction are required.

Claim Rejections - 35 USC112, first paragraph-Enablement

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1638

Claims 42-55 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling AgNO₃ at a concentration of 1 –10mg/l, and culturing the tissues for 2 or 3 days after inoculation with AgNO₃ in the medium (1-10 mg/l), is not enabled for unspecified conditions which do not contain specific AgNO₃ concentration, specific time durations, and temperature conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant provides a number of working examples, detailed information about protocols, and results in the specification. However, while the specification can provide clarification of elements which are known to one skilled in the art, *essential steps and conditions not known to one of ordinary skill in the art are unpredictable*, and must be recited in the claims. Applicant provides no guidance for the treatment conditions of the co-cultivation of the Agrobacterium and the plant cell or tissue in terms of duration of the cocultivation period. Applicant provides a range of concentrations of AgNO₃ in the claimed invention (claims 43 and 44), however for the claimed method to be enabled, guidance must be given for both the concentration of AgNO₃ and the duration of co-cultivating period. Testing the parameters of concentration and of duration times would require a myriad of experiments, comprising an infinite number of combinations of variables. In the absence of such guidance, Applicant has provided no guidance on how to predictably eliminate inoperable embodiments from a virtually ad

Art Unit: 1638

infinitum of possibilities other than by random trial and error, which is excessive experimentation and an undue burden.

In view of the breadth of the claims (any plant cell or tissue, any *Agrobacterium*, any nucleotide sequence of interest, any concentration of AgNO₃, and any duration of cocultivation time) and the lack of guidance in the specification, undue experimentation would be required to enable the invention as commensurate in scope with the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102(b)

7. Claims 42-46 are rejected under 35 U.S.C. 102(b) as being anticipated by De Block, M, et al, Plant Physiol, 1989, vol 91, 694-701.

De Block teaches a method of transforming plant cell or tissue with a nucleotide of sequence of interest comprising cocultivation of *Agrobacterium* with AgNO₃ with plant tissue (Abstract; p 695, 1st paragraph and Table II) and placing the tissue on selective medium comprising AgNO₃ (2-10 mg/L) to select a transformed plant cell or tissue comprising the nucleotide sequence of interest.

Since Applicant gives no time duration for the cocultivation condition, the duration can be infinitely large to infinitely small. Lack of a duration term for the cocultivation of

Art Unit: 1638

Agrobacterium plus AgNO₃ also points to the noncriticality of this treatment, since the time can be any and every time period.

Applicant traverses, stating primarily that in the materials and methods section of DeBlock (Response, p. 6), explants were transferred to a regeneration medium containing AgNO₃ only after co-cultivation with Agrobacterium had finished and the Agrobacterium had been killed by an antibiotic. Applicant cites page 695, "After 3 d the hypocotyl segments were washed with A2 medium containing 500 mg/l carbenicillin". Applicant further states that A2 medium does not contain AgNO₃, and carbenicillin is an antibiotic that ended the cocultivation by killing Agrobacterium.

Applicant's traversal has been considered and is unpersuasive. DeBlock (pages 694-695 bridging) says to the petri dishes containing infection medium, A2, and containing the plant tissue, Agrobacterium was added. "These plates were incubated at low light intensity. After 2 d. the hypocotyl segments were washed with A2 medium containing 500 mg/L carbenicillin, patted dry, and placed on selective medium" (containing AgNO₃). DeBlock did not state that the Agrobacterium were killed by treatment with carbenicillin. It is well known that carbenicillin is an antibiotic which does not kill Agrobacterium instantaneously, rather carbenicillin kills only actively growing Agrobacterium cells and does so in a gradual manner. Furthermore, since there is no specified duration of the cocultivation period in the claimed invention, this can be any time period, from infinitely small to infinitely large.

Art Unit: 1638

8. Claims 42-44 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by Orlikowska, T., et al. Influence of silver nitrate on regeneration and transformation of roses. Journal of Applied Genetics, (1996) Vol. 37 App. 122-125. Meeting Information: International Conference on Perspectives, Warsaw, Poland, September 16-17, 1996.

Orlikowska teaches a method of transforming plant cell or tissue with a nucleotide of sequence of interest comprising cocultivation of Agrobacterium with AgNO₃ (10 mg/ml) with plant tissue (page 123, 3rd ¶)) and placing the tissue media comprising AgNO₃ (10 mg/L) to select a transformed plant cell or tissue comprising the nucleotide sequence of interest.

Accordingly, Orlikowska anticipates the claimed invention.

Accordingly, De Block anticipates the claimed invention.

Claim Rejections - 35 USC § 103

Double Patenting

9. The nonstatutory double patenting rejection is extended to new claims 42-55. Fulfillment of requirements to overcome this rejection will be held in abeyance until allowable subject matter is indicated, per Applicant's request.

Remarks

10. No claim is allowed.

Art Unit: 1638


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. Note that Examiner's phone number will change to 571-272-0796 as of 6 January 2004. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner, art unit 1638
December 13, 2003




PHUONG T. BUI
PRIMARY EXAMINER